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EXAMINER	
LOCKARD, JON MCCLELLAND	
ART UNIT	**PAPER NUMBER**
1647	

DATE MAILED: 09/21/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/031,589	OTA ET AL.	
	Examiner	Art Unit	
	Jon M Lockard	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 July 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,5-10 and 13-15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,5-10 and 13-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-16* are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *23 January 2002* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☒ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *7/01/02,8/29/02*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group I, claims 1-3, -10, and 13-15, in the reply filed on 26 July 2004 is acknowledged.

2. Applicant's election of Group B, SEQ ID NOS:3 and 4, in the reply filed on 26 July 2004 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

3. Claims 4, 11-12, and 16 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 26 July 2004. The Examiner recognizes Applicant's right to pursue additional subject matter in other applications.

4. Claims 1-3, 5-10, and 13-15, as they are drawn to polynucleotides of SEQ ID NO:3, polypeptides of SEQ ID NO:4, vectors and host cells, methods of producing the polypeptides of SEQ ID NO:4, and methods of producing the polynucleotides of SEQ ID NO:3, are currently pending.

Priority

5. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file (Japanese application 11/209817, filed 23 July 1999). Should applicant desire to obtain the benefit of foreign priority under 35 U.S.C. 119(a)-(d) prior

to declaration of an interference, a translation of the foreign application should be submitted under 37 CFR 1.55 in reply to this action.

Information Disclosure Statement

6. The information disclosure statements (IDS), filed 01 July 2002 and 29 August 2002, have been considered by the examiner. Reference A1 has been considered to the extent of the abstract only, as the remainder of the reference is not in the English language. Since no sequence alignment has been provided for the sequence listed therein, the Examiner cannot determine if said sequences constitute prior art.

Drawings

7. Figure 1 should be designated by a legend such as --Prior Art-- because only that which is old is illustrated. See MPEP § 608.02(g). Corrected drawings in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. The replacement sheet(s) should be labeled "Replacement Sheet" in the page header (as per 37 CFR 1.121(d)) so as not to obstruct any portion of the drawing figures. If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

8. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code (see page 2, line 28, page 3, lines 18-20, and page 8, line 7, for example). Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

Claim Objections

9. Claims 1-3, 5-10, and 13-15 are objected to because of the following informalities: Claim 1 encompasses non-elected inventions, e.g., SEQ ID NOS:1, 5, and 7 in part (a) and SEQ ID NOS:2, 6, and 8 in part (b) of claim 1. Appropriate correction is required.

10. Claim 8 is also objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should refer to other claims in the alternative only, and cannot depend from any other multiple dependent claim. For unacceptable multiple dependent claim wording, see MPEP § 608.01(n) *B.* 3., for an example showing reference to two sets of claims to different features, and § 608.01(n) *B.* 4., for an example showing reference back to another multiple dependent claim.

11. Claim 13 is objected to as being of improper dependent form for the recitation "the primer of claim 10". Claim 10 is a "use" claim and not a claim to a primer. Appropriate correction is required.

Claim Rejections - 35 USC § 101 and 35 USC §112

12. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.
>
> The following is a quotation of the first paragraph of 35 U.S.C. 112:
>
> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly

connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

13. Claim 10 provides for the use of the oligonucleotide of claim 9 as a primer for synthesizing a polynucleotide, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced. Claims 13-15 are also rejected as they are either directly or indirectly dependent upon claim 10.

14. Claims 1-3, 5-10, and 13-15 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific, substantial, and credible asserted utility or a well established utility. Novel biological molecules lack an established utility and must undergo extensive experimentation to determine an appropriate specific, substantial, and credible utility.

15. The instant application discloses a polynucleotide set forth as SEQ ID NO:3 encoding a polypeptide set forth as SEQ ID NO:4, partial peptides of SEQ ID NO:4 or polypeptides encoded by nucleic acids that are 70% identical to SEQ ID NO:3 or that will hybridize under any conditions to SEQ ID NO:3, polynucleotides having at least 70% sequence identity to SEQ ID NO:3 and the proteins encoded by them, and methods of producing the proteins and polynucleotides. The specification asserts "analysis of a full-length cDNA provides valuable information" (page 2, line17) and are "extremely valuable in empirical analysis of gene function and in industrial application" (page 2, lines 19-20). However, the instant specification does not teach any physiologic ligands or functional characteristics of the novel polypeptide set forth in SEQ ID NO:4 or encoded by the disclosed nucleic acid set forth in SEQ ID NO:3. Further, the

protein comprising SEQ ID NO:4 or encoded by said disclosed nucleic acid has never been expressed in a cell or organism or assayed for functional activity. The amino acid set forth in SEQ ID NO:4 has been deduced from the nucleic acid sequence (see page 4, lines 10-13). There is no well-established utility for a specific nucleic acid or amino acid sequence and the specification fails to disclose a specific and substantial utility for the claimed invention.

16. The specification asserts the following as patentable utilities for the claimed polynucleotides of SEQ ID NO:3, vectors and transformants comprising the polynucleotides, and polypeptides of SEQ ID NO:4, and methods of producing said polynucleotides and polypeptides:

> 1) The polynucleotide (SEQ ID NO:3) and the polypeptide encoded by it (SEQ ID NO:4) can be used to analyze its biological functions (pg 7, lines 13-35);
>
> 2) The polypeptide (SEQ ID NO:4) can be used to analyze the relationship between the protein and diseases by using the Online Mendelian Inheritance in Man database (pg 8, lines 5-7);
>
> 3) The polypeptide (SEQ ID NO:4), *if* associated with a disease, is useful in drug development (pg 8, lines 8-10);
>
> 4) The polypeptide (SEQ ID NO:4) and partial peptides of SEQ ID NO:4 may be used for raising antibodies (pg 13, lines 13-14);
>
> 5) The polynucleotide (SEQ ID NO:3) may be used for examination and diagnosis of the abnormality of the protein (SEQ ID NO:4);
>
> 6) The polynucleotides may be used in gene therapy (pg 16, lines 1-2);
>
> 7) The polynucleotide of SEQ ID NO:4 or fragments thereof may be used as primers for PCR (pg 15, lines 15-18);
>
> 9) The polypeptides and polynucleotides, *if* associated with a disease, are useful as diagnostic markers (pg 17, lines 6-8); and
>
> 10) The polypeptides and polynucleotides are useful in medical development as probes for searching a compound that regulates their expression and activities, or as targets of gene therapy (pg 17, lines 8-10).

17. These asserted utilities are neither specific nor substantial because they do not identify or reasonably confirm a "real world" context of use. The specification neither identifies the biological functions of the claimed DNA and the protein encoded by it, nor any diseases that are associated with the claimed molecules. Without any biological activity or link to a disease, such constitutes further research to determine the properties of the claimed protein or partial peptides of SEQ ID NO:4 or the nucleic acids encoding them, which is insufficient to meet the requirement of 35 USC § 101.

18. These activities and functions are conjectural and are based solely on the identification of SEQ ID NO:3 as being a novel full-length cDNA. While it is credible that SEQ ID NO:3 is a full-length cDNA, its identification as such is not sufficient to establish either a well known, or a specific, substantial and credible utility. There is no ligand identified that binds to the protein encoded by it, no signaling pathway with which it is involved, and no disease or disorder correlated with the polypeptide. Since the instant specification does not disclose how to use the polypeptide of SEQ ID NO:4, a skilled artisan would not know how to use nucleic acids encoding the polypeptide (SEQ ID NO:3) and methods of making the polynucleotides would not have a patentable utility.

19. A complete lack of the predicted function of the protein and the nucleic acid encoding it supports the notion that further research would be required to confirm a "real world" context of use. It is possible that, after further characterization, this nucleic acid and the protein encoded by it might be found to have a patentable utility, in which case proteins would have a specific utility, or the protein might be found to be associated with a specific disease.

20. In Brenner v. Manson, 148 U.S.P.Q. 689 (Sup. Ct., 1966), a process of producing a novel compound that was structurally analogous to other compounds which were known to possess anti-cancer activity was alleged to be useful because the compound produced thereby was potentially useful as an anti-tumor agent in the absence of evidence supporting this utility. The court expressed the opinion that all chemical compounds are "useful" to the chemical arts when this term is given its broadest interpretation. However, the court held that this broad interpretation was not the intended definition of "useful" as it appears in 35 U.S.C. § 101, which requires that an invention must have either an immediately obvious or fully disclosed "real world" utility. The instant claims are drawn to a protein which has undetermined function or biological significance. Until some actual and specific activity or significance can be attributed to the protein identified in the specification as SEQ ID NO:1 or the polynucleotide encoding it (SEQ ID NO:2, the claimed invention is incomplete.

21. Claims 1-3, 5-10, and 13-15 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific, substantial and credible asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to make/use the claimed invention.

22. Furthermore, even if the protein of SEQ ID NO:4 or the DNA of SEQ ID NO:3 that encodes SEQ ID NO:4 were to have a patentable utility, the instant disclosure would not be found to be enabling for the full scope of the claimed invention.

23. Claim 1, from which claims 2-3, 5-10, and 13-15 depend, recites a polynucleotide sequence encoding the protein of SEQ ID NO:4 in which one or more amino acids are substituted, deleted, inserted, and/or deleted, as well as a polynucleotide that hybridizes with the polynucleotide of SEQ ID NO:3, and a polynucleotide comprising a nucleotide sequence with at least 70% identity to SEQ ID NO:3, with no requirement for conserved structure or function. While it is noted that the claim contains the limitation that the polynucleotide must encode a polypeptide that is functionally equivalent of SEQ ID NO:4, there are no functions of SEQ ID NO:4 disclosed in the specification (See 35 USC § 101 rejection *supra*). Claim 2 recites a protein encoded by any of the aforementioned polynucleotides, and claim 3 recites a partial peptide of the protein of claim 2. Claim 9 recites an oligonucleotide that comprises 15 nucleotides or more of the polynucleotides of claim 1, as well as a nucleotide sequence complementary to the complementary strand of the polynucleotides of claim 1. Lastly, claims 13-15 recite a method of synthesizing a polynucleotide using an oligonucleotide that comprises 15 nucleotides or more of any of the polynucleotides of claim 1. However, other than the protein of SEQ ID NO:4 and the DNA of SEQ ID NO:3 that encodes the protein, the disclosure fails to provide sufficient guidance and information regarding the structural and functional requirements commensurate in scope with what is encompassed by the instant claims. The disclosure has not shown (1) which portions of SEQ ID NO:4 are critical to the activity of the protein of SEQ ID NO:4 (which is itself unknown); (2) what modifications (e.g., substitutions, deletions, or additions) one can make to SEQ ID NO:4 that will result in protein variants or fragments with the same activity as the protein of SEQ ID NO:4; and (3) any guidance on how to use partial peptides of SEQ ID NO:4 which would, based on the language of said claims, encompass both

active and inactive variants of SEQ ID NO:4, or the nucleic acids the encode the aforementioned peptides. The state of the art is such that the relationship between the sequence of a protein and its activity is not well understood and unpredictable, and that certain positions in the sequence are critical to the protein's structure/function relationship and can only tolerate only relatively conservative substitutions or no substitutions (See Wells, 1990, Biochemistry 29:8509-8517; Ngo et al., The Protein Folding Problem and Tertiary Structure Prediction, 1994, pp. 492-495).

24. Due to the large quantity of experimentation necessary to generate the infinite number of derivatives recited in the claims, the lack of direction/guidance presented in the specification regarding which structural features are required in order to provide activity, the absence of working examples directed to the same, the complex nature of the invention, the state of the prior art which establishes the unpredictability of the effects of substitutions/deletions on protein structure and function, and the breadth of the claims which fail to recite any structural or functional limitations, undue experimentation would be required of the skilled artisan to make and/or use the claimed invention in its full scope.

25. Claims 1-3, 5-10, and 13-15 are also rejected under 35 USC 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was files, had possession of the claimed invention.

26. Claim 1, from which claims 2-3, 5-10, and 13-15 depend, recites a polynucleotide sequence encoding the protein of SEQ ID NO:4 in which one or more amino acids are substituted, deleted, inserted, and/or deleted, as well as a polynucleotide that hybridizes with the

polynucleotide of SEQ ID NO:3, and a polynucleotide comprising a nucleotide sequence with at least 70% identity to SEQ ID NO:3. Claim 2 recites a protein encoded by any of the aforementioned polynucleotides, and claim 3 recites a partial peptide of the protein of claim 2. Claim 9 recites an oligonucleotide that comprises 15 nucleotides or more of the polynucleotides of claim 1, as well as a nucleotide sequence complementary to the complementary strand of the polynucleotides of claim 1. Lastly, claims 13-15 recite a method of synthesizing a polynucleotide using an oligonucleotide that comprises 15 nucleotides or more of any of the polynucleotides of claim 1. The claims do not require that the proteins and nucleic acids possess any particular biological activity (it is noted that claim 1 contains the limitation that the polynucleotide must encode a polypeptide that is functionally equivalent of SEQ ID NO:4, however, there are no functions of SEQ ID NO:4 disclosed in the specification), nor any particular conserved structure, or other disclosed distinguishing feature. Thus, the claims are drawn to a genus of protein and its homologues, a genus of DNA molecules, and a method of making said genus of proteins and DNA molecules.

27. To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, and any combination thereof. In this case, the only factor present in the claims is a partial structure in the form of a recitation of percent identity, a recitation of hybridizes to the polynucleotide of SEQ ID NO:3, and encoding a polypeptide that is "functionally equivalent" to SEQ ID NO:4. The specification does not identify any particular

portion of the structure that must be conserved, nor does it provided any disclosure of a particular structure/function correlation or biological activity. The distinguishing characteristics of the claimed genus are not described. The only adequately described species is a polynucleotide represented by SEQ ID NO:3 and a polypeptide encoded by SEQ ID NO: 4. Accordingly, the specification does not provide adequate written description of the claimed genus.

28. *Vas-Cath Inc. v. Mahurkar*, 19USPQ2d 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116).

29. With the exception of the sequences referred to above, the skilled artisan cannot envision the detailed chemical structure of the encompassed polypeptides and DNA molecules nor the methods of making them, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The nucleic acid itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

30. One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to

lack of written description for that broad class. The specification provided only the bovine sequence.

31. Therefore, only the protein of SEQ ID NO:4 and the DNA encoding the protein (SEQ ID NO:3 or degenerate variants thereof), but not the full breadth of the claims meet the written description provision of 35 U.S.C. §112, first paragraph. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

32. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

33. Claims 1-3, 5-10, and 13-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

34. Claim 1 is indefinite because it recites the phrase "functionally equivalent" (lines 12 and 16). Since neither the art nor the Specification provides a function of the disclosed polynucleotide or the polypeptide encoded by it, the claim is indefinite. Furthermore, even if a known function was disclosed, it would be unclear what parameters and to what degree these parameters must be met in order to be considered "functionally equivalent". Claims 2-3, 5-10, and 13-15 are also rejected as they are either directly or indirectly dependent upon claim 1.

35. Claim 3 is indefinite for reciting a "partial peptide". Without knowing the minimum length of the "partial peptide", the metes and bounds of the claim cannot be determined. Claim 8 is also rejected as it is either directly or indirectly dependent upon claim 3.

36. Claim 6 is indefinite because it recites the term "carrying". Since neither the art nor the Specification provides an unambiguous definition of the term, the claim is indefinite. Amendment to read "An isolated cell comprising the polynucleotide..." would be remedial.

37. Claim 7 is indefinite because it recites the phrase "expressively carrying". Since neither the art nor the Specification provides an unambiguous definition of the term, the claim is indefinite. Claim 8 is also rejected as it is either directly or indirectly dependent upon claim 7.

38. Claims 6 and 7 are further rejected as being indefinite because it is not clear whether the limitation "a transformant" is intended to indicate an isolated host cell, a transgenic animal, or a human.

39. Claim 9 is indefinite because it recites the phrase "complementary to the complementary strand". Since neither the art nor the Specification provides an unambiguous definition of the term, the claim is indefinite. The complement of the complement is the same as the starting material. Accordingly, it is not clear what the applicants intend by this limitation. Claim 10 is also rejected as it is either directly or indirectly dependent upon claim 9.

40. Claim10 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

41. Claims 14-15 are rejected as being indefinite because it is unclear of the meaning of the term "obtainable" in line 1 of the claims. The term "obtainable" merely indicates that the library

or complementary strand could be so obtained. Therefore, it is not clear how this recitation in claims 14 and 15 further limits the method of claim 13.

Claim Rejections - 35 USC § 102

42. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

43. Claims 1-3, 5-10, 13, and 15 are rejected under 35 U.S.C. 102(e) as being anticipated Drmanac et al. (US 2003/0073623 A1, published on April 17, 2003; priority date, January 20, 1999).

44. Due to the unclear claim language, see 112¶2 rejections *supra*, a completely meaningful search of the prior art could not be made. However, Drmanac et al teach a nucleic acid sequence (SEQ ID NO:1667) that shows 92% identity to SEQ ID NO:3 with 100% identity from position 994-1428 of SEQ ID NO:3 (See attached sequence alignment).

45. Drmanac et al. also teach expression vectors containing the nucleic acid sequence, host cells transformed with these expression vectors, and a method for the production and recovery of the purified polypeptides from the host cells (See page 1, paragraph 11). Drmanac et al. also teach isolated peptides encoded by the nucleic acid of SEQ ID NO:1667 as well as fragments of

the polypeptide. Drmanac et al. also teach oligomers of the nucleic acid sequence that are that are useful as primers for synthesizing polynucleotides using PCR (See page 1, paragraph 12 and page 14, paragraph 187). Lastly, Drmanac et al. teach a method of synthesizing a polynucleotide using a cDNA library as a template and standard PCR techniques (See page 8, paragraph 107.

46. Thus, Drmanac et al. anticipate the limitations of claims 1-3, 5-10, 13, and 15.

Claim Rejections - 35 USC § 103

47. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

48. Claim14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Drmanac et al. as applied to claims 1-3, 5-10, 13, and 15 above, and further in view of Maruyama et al. (Gene 138:171-174, 1994; Cited by Applicant).

49. The primary reference (summarized above) teaches a method of synthesizing a polynucleotide using a cDNA library as a template and standard PCR techniques (See page 8, paragraph 107.

50. The primary reference does not disclose that the cDNA library was obtained by oligo-capping.

51. Maruyama et al. teach oligo-capped mRNAs are useful for the construction of a cDNA library (See page 1, ¶2).

52. At the time of the invention it would have been obvious to a person of ordinary skill in the art to modify the teachings of Drmanac et al. and synthesize a polynucleotide using a cDNA library constructed from olio-capped mRNAs as taught by Maruyama et al.

53. The person of ordinary skill in the art would have been motivated to do so by the disclosure by Maruyama et al. that oligo-capped mRNAs are useful for the construction of a cDNA library which can be used for identification of full-length cDNA clones. This would be considered an expected advantage when the goal of synthesizing the polynucleotide is to obtain the full-length clone for establishing the coding sequence and promoter region of a gene, as taught by Maruyama et al (See page 1, ¶1).

Summary

54. No claim is allowed.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Jon M. Lockard, Ph.D.** whose telephone number is **(571) 272-2717**. The examiner can normally be reached on Monday through Friday, 8:00 AM to 6:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Brenda Brumback, Ph.D.** can be reached on **(571) 272-0961**.

The fax number for the organization where this application or proceeding is assigned is **703-872-9306**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see **http://pair-direct.uspto.gov**. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at **866-217-9197** (toll-free).

JML
September 14, 2004

LORRAINE SPECTOR
PRIMARY EXAMINER